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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,058	03/13/2006	Zhuangrong Sun	8231.015	2320
28410	7590	02/13/2008	EXAMINER	
BERENATO, WHITE & STAVISH, LLC			CHU, YONG LIANG	
6550 ROCK SPRING DRIVE				
SUITE 240			ART UNIT	PAPER NUMBER
BETHESDA, MD 20817			1626	
			MAIL DATE	DELIVERY MODE
			02/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/541,058	SUN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Yong Chu	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 August 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 17-23 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 17-23 is/are rejected.
- 7) Claim(s) 17 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>03/13/2006</u> .	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

Claims 10-17 have been canceled by the amendment filed on 08/28/2007.

Claims 17-23 are new by the amendment. Therefore, claims 17-23 are pending in the instant application.

### ***Information Disclosure Statement***

Applicants' Information Disclosure Statement, filed 03/13/2006 has been considered. Please refer to Applicant's copy of the PTO-1449 submitted herewith.

### ***Priority***

This Application is a 371 of PCT/CN03/01145 filed on 12/30/2003, and claims the benefit of foreign priority of China Patent Application No. 02159419.8, filed on 12/31/2002.

### ***Response to Restriction/Election***

Applicant' election without traverse of Group II (claim 10) a method of treating inflammation comprising administering an anti-inflammatory analgesic drug comprising a compound of formula (I), in the reply filed 06/19/2007 is acknowledged. Since Applicants have amended claims and added new dependent method claims, all the pending method claims 17-23 will be examined on the merits.

***Specification***

The first paragraph of the specification does not contain continuing data to which the instant specification claims benefit from. An appropriate amendment is required.

***Claim Objections***

The amendment to the claims filed on 08/28/2007 does not comply with the requirements of 37 CFR 1.121(c) because claim 17 was numbered previously, and can not be numbered again in the new claim. Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.126 which states: the original numbering of the claims must be preserved throughout the prosecution. When claims are canceled the remaining claims must not be renumbered. When claims are added, they must be numbered by the applicant consecutively beginning with the number next following the highest numbered claim previously presented (whether entered or not). Appropriate correction is requested.

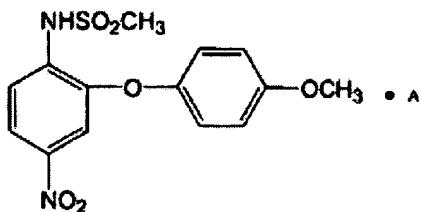
***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 17 is rejected under 35 U.S.C. 102 (b) as being anticipated by Moore et al., U.S. Patent No. 3,840,597 ("the '597 patent").

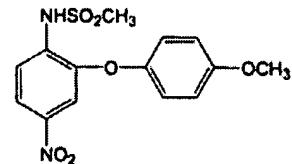
Applicants' claims relate to a method of treating inflammation, comprising administering an anti-inflammatory analgesic drug comprising a compound of formula (I)



Formula (I)

wherein A is present or absent and represents a pharmaceutically acceptable inorganic or organic base, or a basic amino acid,

or a pharmaceutically acceptable salt thereof, or a mixture thereof with povidone, phospholipids or cyclodextrin.



The '597 patent disclosed a specific compound (CAS RN 51765-76-5) or a pharmaceutical composition comprising the compound of formula (I) as an anti-inflammatory agent, and a method for controlling inflammation in mammalian tissue by using the compound thereof at lines 61-69 of column 1, and line 19-21 of column 13. The specific compound disclosed at lines 19-21 of column 13 as 2-(4-methoxyphenoxy)-4-nitromethane-sulfonanilide. Therefore, the '597 patent anticipates the instant claim 17.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

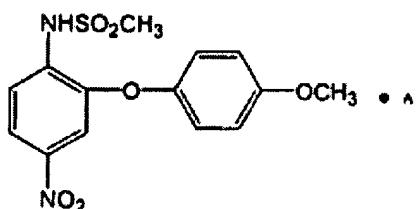
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17-23 are rejected under 35 U.S.C. 103 (a) as unpatentable over the '597 patent in view of the teaching by Pirotte et al., U.S. Patent No. 5,756,546 ("the 546 patent").

Applicants' claims relate to a method of treating inflammation, comprising administering an anti-inflammatory analgesic drug comprising a compound of formula (I)

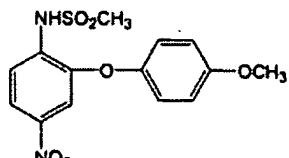


Formula (I)

wherein A is present or absent and represents a pharmaceutically acceptable inorganic or organic base, or a basic amino acid,

or a pharmaceutically acceptable salt thereof, or a mixture thereof with povidone, phospholipids or cyclodextrin.

Determination of the scope and content of the prior art (MPEP §2141.01)

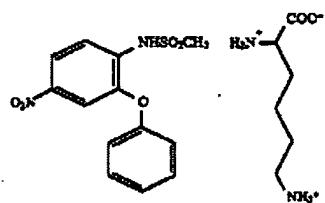


The '597 patent disclosed a specific compound

(CAS RN

51765-76-5) or a pharmaceutical composition comprising the compound of formula (I) as an anti-inflammatory agent, and a method for controlling inflammation in mammalian tissue by using the compound thereof at lines 61-69 of column 1, and line 19-21 of column 13. The specific compound disclosed at lines 19-21 of column 13 is 2-(4-methoxyphenoxy)-4-nitromethane-sulfonanilide. At lines 1-31, column 3, the various salts of the compound are further disclosed for the instantly claimed application, which includes the inorganic salts, and the organic amine salts such as morpholine, or methyl cyclohexylamine.

The '546 patent disclosed a water-soluble nimesulide-L-lysine salt



Nimesulide-L-lysine salt

or nimesulide-L-arginine, optionally further comprising

cyclodextrins and a method of using the compounds or composition for treating inflammation.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the '597 patent method and the instantly claimed method, is that the prior art reference teaches the method using

compound or a organic amino salt, or a composition comprising said compound, but does not specifically teach the salts as trans-4-methyl (or t-butyl)-cyclohexylamine, lysine, arginine, or further comprising cyclodextrins.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

To those skilled in the art, such differences are in the grasp of one ordinary skilled in the art. The '597 patent disclosed the organic amine base can be methyl-cyclohexylamine. To one ordinary skilled in the art, the trans-methyl and t-butyl cyclohexylamine are obvious to the methyl cyclohexylamine salt, because they are either isomer or analogs, and all function as a base for making the corresponding salt. The use of lysine, or arginine as a base, or further comprising cyclodextrins is also taught and/or suggested by the '546 patent. The form of the claimed drug as oral preparation, injection, suppository, drop, or preparation for external use is obviousness to one skilled in the medicinal chemistry art, because such forms are the ordinary forms of drug formulation for treating inflammation. Without further disclosure of unexpected prosperities, the instantly claimed method obvious to the combination as whole of the prior art teaching, and the instant claimed method would have been suggested to one skilled in the art.

***Conclusion***

- Specification is objected to.
- Claim 17 is objected to.
- Claims 17-23 are rejected.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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